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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Oshlack et al.	Confirmation No.:	7218
Serial No.:	10/706,496	Art Unit:	1617
Filed:	November 12, 2003	Examiner:	Edward J. Webman
For:	CONTROLLED RELEASE OXYCODONE COMPOSITIONS	Attorney Docket No.:	305158-999276 (6750-278-999)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

Enclosure accompanying this Information Disclosure Statement is a List of References Cited by Applicants (References **AO1-A02; B01-B04; and C01-C81).**

This application is a continuation application under 37 C.F.R. §1.53(b) or (d). Copies of the above references were previously submitted by Applicants and/or cited by the Examiner in prior Application Nos. 10/163,484, filed June 5, 2002; 09/933,411, filed August 20, 2001; 09/784,888, filed February 16, 2001; 09/481,909, filed January 12, 2000; 08/909,328, filed August 11, 1997; 08/618,344, filed March 19, 1996, now Patent No. 5,656,295; 08/081,302, filed June 18, 1993, now Patent No. 5,549,912; and 07/800,549, filed November 21, 1991, now Patent No. 5,266,331, to all of which this application claims priority under 35 U.S.C. §120. Therefore, copies of the references cited in the List of References Cited by Applicants in this Information Disclosure Statement are not being submitted pursuant to 37 C.F.R. §1.98(d). However, should the Examiner request copies of the references, Applicants would be happy to provide them.

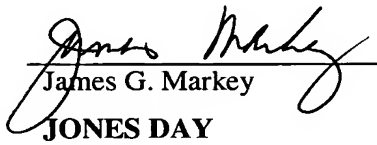
This Information Disclosure Statement supplements the Information Disclosure Statement filed on November 12, 2003.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R §1.97(b), but before the mailing date of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the $180.00 fee set forth in 37 C.F.R. §1.17(p) and any other fees that may be due in connection with this filing to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed.

No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made. 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: March 17, 2005



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Enclosures

ATTY DOCKET NO.	APPLICATION NO.
305158-999276 (6750-278-999)	10/706,496
APPLICANT	
Oshlack et al.	
FILING DATE	GROUP
November 12, 2003	1617

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	4,235,870	11/15/1980	Leslie			
	A02	5,266,311	11/30/1993	Cerretti et al.			
	A03						
	A04						
	A05						
	A06						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	B01	DE 32 46 492	06/30/1983	Germany			X	
	B02	EP 0 249 347	12/16/1987	EPO				
	B03	CA 1,296,633	03/03/1992	Canada				
	B04	CA 1,297,025	03/10/1992	Canada				
	B05							
	B06							
	B07							
	B08							

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	C01	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1987; (7th ed.):3-172.
	C02	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1988; (8th ed.):3-179
	C03	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1989; (9th ed.):3-199.
	C04	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1990; (10th ed.):3-200.
	C05	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1991; (11th ed.):3-200.
	C06	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1992; (12th ed.):3-197.
	C07	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1993; (13th ed.):3-198.
	C08	April 11, 2004 Amicus Curae Brief of Guilford Pharmaceuticals in Support of Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company and EuroCeltique S.A. in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant-Appellee), Endo Pharmaceuticals Holdings Inc. (Defendant-Appellee)*, United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226
	C09	April 2, 2004 Corrected Brief of Plaintiffs-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant-Cross Appellant), Endo*

		Pharmaceuticals Holdings Inc. (Defendant-Cross Appellant), United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226
	C10	August 3, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Teva Pharmaceuticals USA to Euro-Celtique S.A.
	C11	Black: A rational approach to cancer pain management. J. of Family Practice. 1989;28(3):267-8.
	C12	Chang et al. Sustained drug release from tablets and particles through coating.
	C13	Codeine. *Available at* http://esc.syrres.com/interkow/webprop.exe.
	C14	Codeine. Clark's Isolation and Identification of Drugs. 1986;490-1.
	C15	Codeine. The Merck Index 1989;(11th ed.):384-5.
	C16	Endo's February 17, 2004 Memorandum in support of its Motion for Relief from Order with respect to Infringement in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)* Civil Action Nos. 00-CV 8029 (SHS); 01-CV 2109 (SHS) and 01-CV 8177(SHS)
	C17	Endo's March 19, 2004 Reply Memorandum in support of its Motion for Relief from Order with respect to Infringement in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)* Civil Action Nos. 00-CV 8029 (SHS); 01-CV 2109 (SHS) and 01-CV 8177(SHS)
	C18	February 25, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company
	C19	February 25, 2003 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10, 20 and 40 mg, from Teva Pharmaceuticals USA to Purdue Pharma L.P., The P.F. Laboratories, Inc. and Euro-Celtique S.A.
	C20	February 9, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10 and 20 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
	C21	Foldes. Role of oral and parenteral drugs in the management of intractable pain. Pain. 1988;9:286-9.
	C22	Gibaldi. Prolonged-release medication. Biopharmaceutics and Clinical Phamakokinetics. 1984 (3rd ed);27:113-130.
	C23	Gibaldi. Prolonged-release medication. Biopharm. and Clin. Pharmcokinetics. 1991;(4th ed.):124-45.
	C24	Guay et al. Pharmacokinetics of codeine after single- and multiple-oral-dose administration to normal volunteers. J Clin Pharmacol. 1987 Dec;27(12):983-7.
	C25	Hydromorphone. *Available at* http://esc.syrres.com/interkow/webprop.exe.
	C26	Hydromorphone. Clarke's Isolation and Identification of Drugs. 1986; 667-8.
	C27	Hydromorphone. The Merck Index. 1989;(11th ed.):762.
	C28	IMS Study (D18).
	C29	Inturrisi, Role of opioid analgesics. Am J Med. 1984 Sep 10;77(3A):27-37.
	C30	Inturrisi. Management of cancer pain pharmacology and principles of management. Cancer. 1989 June;63:2308-20.
	C31	July 31, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
	C32	June 16, 2004 Reply Brief of Plaintiffs-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant- Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant- Cross Appellant)*, United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226, -1347, -1357
	C33	June 30, 2004 Reply Brief of Defendants/Cross-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant- Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant- Cross Appellant)*, United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1347, -1357
	C36	Kalso et al. Morphine and oxycodone hydrochloride in the management of cancer pain. Clin Pharmacol Ther. 1990 May;47(5):639-46.
	C35	Khojasteh et al. Controlled-release oral morphine sulfate in the treatment of cancer pain with pharmacokinetic correlation. J Clin Oncol. 1987 Jun;5(6):956-61.
	C36	Lee et al. Methods to achieve sustained drug delivery. The physical approach: Oral and parenteral dosage forms. Sustained and Controlled Release Drug Delivery Systems. 1978;(3)123-204.
	C37	Lee et al. Methods to achieve sustained drug delivery. The physical approach: Oral and parenteral dosage forms. Sustained and Controlled Release Drug Delivery Systems. 1978;(3)123-209.
	C38	Leow. The clinical pharmacology of oxycodone. A thesis submitted for the degree of Doctor of Philosophy of the University of Queensland. 1993.
	C39	List of known opioids and known opiates.

	C40	Maruta et al. Problems with the use of oxycodone compound in patients with chronic pain. Pain. 1981 Dec;11(3):389-96.
	C41	May 12, 2004 Brief of Defendants/Cross-Appellants in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs/ Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant- Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant- Cross Appellant)*, United States Court of Appeals for the Federal Circuit, Appeals Nos.04-1189, -1226, -1347, -1357
	C42	McKay. Pain management for urological malignancies. Urol Int. 1991;46(3):252-8. Review.
	C43	Mikus. Polymorphic metabolism of opioid narcotic drugs: Possible clinical implications. Annals Acad. of Medicine. 1991 Jan;20(1):10-12.
	C44	Morphine sulfate sustained release. Compendium of Pharmaceutical and Specialties. 1988;572-3.
	C45	Morphine sulfate. *Available at* http://esc.syrres.com/interkow/webprop.exe.
	C46	Morphine. *Available at* http://esc.syrres.com/interkow/webprop.exe.
	C47	Morphine. Clarke's Isolation and Identification of Drugs. 1986;790-1.
	C48	Morphine. The Merck Index. 1989;(11th ed.):988-9.
	C49	Muhtadi et al. Codeine phosphate. Analytical Profiles of Drug Substances. 1981;(10):93-138.
	C50	Muhtadi. Analytical profile of morphine. Analytical Profiles of Drug Substances. 1988;(17):259-366.
	C51	Nichols et al. Oxycodone injection: Pharmacokinetics. Abstracts 10th World Congress on Pain. 2002 Aug;59 (191-P87) *and* Final Study Report.
	C52	November 8, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 160 mg, from Teva Pharmaceuticals USA to Purdue Pharma L.P.
	C53	Oral oxycodone: new preparation. No better than oral morphine. Prescrire Int. 2003 Jun;12(65):83-4.
	C54	Oshlack. Internal memorandum regarding R&D. 1983 Aug.
	C55	Oshlack. Notes on Example 2 of D1. The Purdue Frederick Research Center. 1982.
	C56	Oxycodone HCl trihydrate. Compendium of Pharmaceuticals and Specialties. 1988;879.
	C57	Oxycodone. *Available at* http://esc.syrres.com/interkow/webprop.exe
	C58	Oxycodone. Clark's isolation of Drugs. 1986; 841.
	C59	Oxycodone. The Merck Index. 1989; (11th ed.):1100.
	C60	Parab et al. Pharmacokinetics of hydromorphone after intravenous, peroral and rectal administration to human subjects. Biopharm Drug Dispos. 1988 Mar-Apr;9(2):187-99.
	C61	Pöyhia et al. The pharmacokinetics and metabolism of oxycodone after intramuscular and oral administration to healthy subjects. Br J Clin Pharmacol. 1992 Jun;33(6):617-21.
	C62	Product Information OxyContin (D17c).
	C63	Product Information. 1990; 710-3 (D17a).
	C64	Product Information. 2001 (D17b).
	C65	*Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant) v. EuroCeltique S.A. (Counterclaim Defendant)* 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004), 70 U.S.P.Q.2d 1185
	C66	Purdue's March 12, 2004 Opposition to Endo's Motion for Relief from Order with respect to Infringement in *Purdue Pharma, L.P, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)* Civil Action Nos. 00-Civ 8029 (SHS); 01-Civ 2109 (SHS) and 01-Civ 8177(SHS)
	C67	Ripamonti; Traitement de la douleur et soins palliatifs pour les malades atteints de cancer avancé. Doul. et Analg. 1990;3:75-81 (in French, w/ English abstract).
	C68	Rischitelli et al. Safety and efficacy of controlled-release oxycodone: a systematic literature review. Pharmacotherapy. 2002 Jul;22(7):898-904. Review.
	C69	Robinson et al. Theoretical formulation of sustained-release dosage forms. J Pharm Sci. 1966 Nov;55(11):1254-63.
	C70	Roy et al. Solubility and related physicochemical properties of narcotic analgesics. Pharm Res. 1988 Sep;5(9):580-6.
	C71	Savarese et al. Steady-state pharmacokinetics of controlled release oral morphine sulphate in healthy subjects. Clin Pharmacokinet. 1986 Nov-Dec;11(6):505-10.
	C72	Schneider. The pharmacology of oxycodone and morphine. A thesis submitted for the degree of Doctor of Philosophy in Pharmacy of The University of Queensland. 1989.
	C73	September 24, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10 and 20 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company
	C74	September 4, 2002 Resubmission of August 19, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 40 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company

	C75	September 8, 2000 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 40 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
	C76	Silber et al. Utilizing pharmacokinetic principles in the design of controlled or sustained release formulations. Pharmcodynamics Dept., Med. Res. Div. Am. Cyanamid Co.;1-33.
	C77	Stambaugh et al. Double-blind, randomized comparison of the analgesic and pharmacokinetic profiles of controlled- and immediate-release oral oxycodone in cancer pain patients. J Clin Pharmacol. 2001 May;41(5):500-6.
	C78	Thomas. Endone. Australia Prescription Products Guide. 1989;1(A-H):646.
	C79	Thomas. Endone. Australia Prescription Products Guide. 1990;1(A-H):676.
	C80	Urquhart. Performance requirements for controlled-release dosage forms: Therapeutic and pharmacological perspectives. Controlled-Release Pharmaceuticals. 1981;1-48.
	C81	Vallner et al. Pharmacokinetics and bioavailability of hydromorphone following intravenous and oral administration to human subjects. J Clin Pharmacol. 1981 Apr;21(4):152-6.

EXAMINER	**DATE CONSIDERED**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.